

### **REMARKS/ARGUMENTS**

Upon entry of this amendment, claims 14-15 and 19-26 are pending in this application and are presented for examination. Claim 14 has been amended. Claims 1-13 and 16-18 have been withdrawn from consideration as being directed to non-elected inventions. Claims 19-26 are newly added, and are drawn to the elected invention. No new matter has been introduced with the foregoing amendments. Reconsideration is respectfully requested.

#### **I. FORMALITIES**

Applicant thanks the Examiner for the telephone interview of January 13, 2005, in which proposed amendments to claim 14 were discussed.

Support for amended claim 14 and new claims 19-26 is found throughout the specification as filed. In particular, support for amended claim 14 is found, for example, on page 6, lines 1-5 and on page 31, lines 10-24. Support for new claim 19 is found, for example, on page 82, lines 17-19. Support for new claim 20 is found, for example, on page 83, lines 6-8. Support for new claims 21-24 is found, for example, on page 6, lines 1-5. Support for new claim 25 is found, for example, on page 82, lines 23-30. Support for new claim 26 is found, for example, on page 7, lines 2-6. Thus, no new matter has been introduced. As such, Applicant respectfully requests that the new claims be entered.

#### **II. SPECIFICATION OBJECTION**

In the Office Action, the Examiner indicated that the specification was objected to because page 31 refers to SEQ ID Nos: 1-146, which are not found in the specification. Applicant has amended the specification on page 31, lines 15-16, to replace the phrase "any one of SEQ ID Nos: 1-146" with "Table 1." Similarly, Applicant has amended the specification on page 85, line 9, and on page 89, line 12, to replace "SEQ ID Nos: 1-146" with "Table 1." Since a skilled person would readily recognize that the term "SEQ ID Nos: 1-146" refers to the 146 IBD genes shown in Table 1, no new matter has been introduced. Thus, Applicant respectfully requests that the amendments to the specification be entered.

The Examiner also indicated that the specification was objected to because the term "selectively hybridize" in claim 14 is not supported by the specification. As discussed

below, Applicant has amended claim 14 to delete this term, thereby rendering this objection moot. Accordingly, Applicant respectfully requests that this objection be withdrawn.

### III. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 14-15 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled the art that Applicant, at the time the application was filed, had possession of the claimed invention. To the extent the rejection is applicable to the amended set of claims, Applicant respectfully traverses the rejection.

The Examiner alleges that the specification does not disclose nucleic acid probes which selectively hybridize to IBD genes. The Examiner also alleges that the claimed IBD genes are not limited to those provided in Table 1 of the specification. In order to expedite prosecution of the present case, Applicant has amended claim 14 to replace the term "selectively hybridize" with "specifically hybridize" and to recite that the IBD genes are represented by those genes listed in Table 1. As a result, claim 14 as amended sets forth a nucleic acid array comprising a solid support and displayed thereon nucleic acid probes which *specifically hybridize* to the mRNA of at least 5 different IBD genes *shown in Table 1*.

Applicant asserts that the specification as filed contains adequate written description of the nucleic acid probes used in the claimed invention. In particular, the specification defines the term "selectively hybridize" as the ability of a nucleic acid probe of the claimed invention to hybridize to at least a portion of a nucleic acid shown in Table 1, *e.g.*, approximately 6, 12, 15, 20, 30, 50, 100, 150, 200, 300, 350, 400, 500, 750, or 1000 contiguous nucleotides, such that the background hybridization to a cellular nucleic acid encoding a different protein is less than 15% (*see*, page 31, lines 10-24). The specification also describes that these nucleic acid probes are at least 12 nucleotides in length and have a sequence complementary to a nucleic acid sequence shown in Table 1, in which the nucleic acid sequence is provided by a GenBank accession number (*see*, page 82, lines 24-30; Table 1, under "Acc No."). Further, the specification discloses that these nucleic acid probes generally hybridize under stringent conditions to the nucleic acid sequence and are at least about 80% identical to the nucleic acid

sequence (*see*, page 6, lines 21-32). Consequently, Applicant believes that the nucleic acid probes used in the claimed invention are adequately disclosed in the specification as filed.

In view of the amendment to claim 14, Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection.

#### **IV. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 14-15 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. To the extent the rejection is applicable to the amended set of claims, Applicant respectfully traverses the rejection.

The Examiner alleges that the term "selectively hybridize" in claim 14 is a relative term which is undefined in the specification. As discussed above, Applicant has amended claim 14 to delete this term and replace it with the term "specifically hybridize," which is defined on page 31, lines 10-24, of the specification as filed. In view of the amendment to claim 14, Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. § 112, second paragraph rejection.

#### **V. REJECTION UNDER 35 U.S.C. § 102(b)/103(a)**

Claims 14-15 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over Dieckgraefe *et al.* (*Gastroenterology*, 114:A964-965 (1998)). To the extent the rejection is applicable to the amended set of claims, Applicant respectfully traverses the rejection.

The Examiner alleges that Dieckgraefe *et al.* discloses the characterization of mucosal gene expression in inflammatory bowel disease by direct hybridization to massively parallel oligonucleotide arrays. In order to expedite prosecution, Applicant has amended claim 14 to recite a nucleic acid array comprising nucleic acid probes which specifically hybridize to the mRNA of at least 5 different IBD genes *shown in Table 1*. Applicant asserts that Dieckgraefe *et al.* provides a general teaching of the different classes of genes displaying differential expression in diseased tissue, but simply fails to teach or suggest the differential expression of any of the *specific IBD genes shown in Table 1* to which the nucleic acid probes

of the claimed invention specifically hybridize. As a result, each and every element as set forth in amended claim 14 is not found in Dieckgraefe *et al.* In view of the foregoing, Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. § 102(b) rejection.

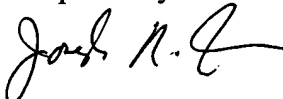
Further, Applicant asserts that one skilled in the art would not have been motivated to modify the teaching of Dieckgraefe *et al.* to arrive at the claimed invention because Dieckgraefe *et al.* does not teach or suggest any of the ***specific IBD genes shown in Table 1*** to which the nucleic acid probes of the claimed invention specifically hybridize. Moreover, one skilled in the art would not have had any reasonable expectation that a nucleic acid array comprising nucleic acid probes which specifically hybridize to ***specific IBD genes shown in Table 1*** would be successful based upon the teaching of Dieckgraefe *et al.* because Dieckgraefe *et al.* simply fails to teach or suggest any specific genes displaying differential expression in diseased tissue. As such, Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. § 103(a) rejection.

## VI. CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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